UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/525,867	03/15/00	YUE H	PF-0678US

HM22/1002

LEGAL DEPT
INCYTE PHARMACEUTICALS INC
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EXAMINER	
TUNG, P	
ART UNIT	**PAPER NUMBER**
1652	7

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/525,867	Yue et al.
Examiner	**Art Unit**
Peter Tung	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-23 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 and 15, drawn to an isolated polypeptide of a specific SEQ ID NO: and a pharmaceutical composition comprising said polypeptide, classified in class 530, subclass 350.

II. Claims 3-6, 8, 10 and 11, drawn to an isolated polynucleotide of a specific SEQ ID NO:, fragments thereof, a transformed host cell and a method of producing a polypeptide, classified in class 536, subclass 23.5.

III. Claim 7, drawn to a transgenic organism comprising a polynucleotide of a specific SEQ ID NO:, classified in class 800, subclass 2.

IV. Claim 9, drawn to an antibody which specifically bind to a polypeptide of a specific SEQ ID NO:, classified in class 530, subclass 387.1.

V. Claims 12-14, drawn to a method for detecting a target polynucleotide comprising a specific SEQ ID NO:, classified in class 530, subclass 350.

VI. Claim 16, drawn to a method comprising administering a pharmaceutical composition comprising a polypeptide of a specific SEQ ID NO:, classified in class 514, subclass 2.

VII. Claim 17, drawn to a method for screening an agonist of a polypeptide of a specific SEQ ID NO:, classified in class 530, subclass 300.

VIII. Claims 18 and 19, drawn to a pharmaceutical composition comprising an agonist of a polypeptide of a specific SEQ ID NO: and a method of using said composition, classified in class 514, subclass 1.

IX. Claim 20, drawn to a method for screening an antagonist of a polypeptide of a specific SEQ ID NO:, classified in class 530, subclass 300.

X. Claims 21 and 22, drawn to a pharmaceutical composition comprising an antagonist of a polypeptide of a specific SEQ ID NO: and a method of using said composition, classified in class 514, subclass 1.

XI. Claim 23, drawn to a method for screening a compound which alters expression of a polynucleotide of a specific SEQ ID NO:, classified in class 530, subclass 300.

2. The inventions are distinct, each from the other because of the following reasons: Each of Groups I-IV, VIII and X is directed to a separate and distinct invention. Group I is directed to a polypeptide of a specific SEQ ID NO:, Group II is directed to a polynucleotide of a specific SEQ ID NO:, fragments and transformed host cell, Group III is directed toward a transgenic organism comprising a polynucleotide of a specific SEQ ID NO:, Group IV is directed to antibodies against a polypeptide of a specific SEQ ID NO:, Group VIII is directed to an agonist of a polypeptide of a specific SEQ ID NO: and Group X is directed to an antagonist of a polypeptide of a specific SEQ ID NO:.

The products of Group I-IV, VIII and X would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

3. Each of Groups II and V-XI is directed to a separate and distinct invention. Group II is directed to a method of producing a polypeptide, Group V is directed to a method of detecting a target polynucleotide comprising a specific SEQ ID NO:, Group VI is directed to a method of treating a disease associated with MITP expression, Group VII is directed to a method of screening an agonist, Group VIII is directed to a method of using an agonist, Group IX is directed to a method of screening an antagonist, Group X is directed to a method of using an antagonist and Group XI is directed to a method of screening a compound which alters expression of a polynucleotide. These methods are distinct both physically and functionally, require different process steps, reagents and parameters and produce different products.

4. Inventions of Group II and I and are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as by peptide synthesis.

5. Inventions of Group I and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as making antibodies against the specific polypeptide.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Upon the election of a group for examination, Applicants are also required to elect either a specific polypeptide SEQ ID NO: 1-8 or specific polynucleotide SEQ ID NO: 9-16, corresponding to the elected group. It is noted that this is not a species election for the elected group as each of the sequences SEQ ID NO: 1-16 are also patentably distinct.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600